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8

9 UNITED STATES DISTRICT COURT
10 NORTHERN DISTRICT OF CALIFORNIA
11
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13 **SHIONOGI & CO., LTD., a Japanese**
14 **company,**

15 **Plaintiff,**

16 **v.**

17 **INTERMUNE, INC., a Delaware**
18 **corporation,**

19 **Defendant.**

Case No. CV-12-3495 EDL

JOINT RULE 26(f) CASE
MANAGEMENT CONFERENCE
REPORT

Date: October 30, 2012

Time: 10:00 a.m.

Judge: Hon. Elizabeth D. Laporte

Court: E, 15th Floor

Pursuant to Rule 26(f) of the Federal Rules of Civil Procedure, Local Rules 16-9 and 26-1, and General Order No. 64, the parties submit the following Joint Case Management Conference Statement. The parties met and conferred pursuant to Rule 26(f) on September 18, 2012. During this conference, the parties discussed the items required under Rule 26 and the General Order, as well as Initial Disclosures and discovery. This Joint Statement was prepared based on those discussions. The parties' agreements reflected herein can be changed by stipulation of the parties or, if necessary, by order of the Court for good cause shown.

1. Jurisdiction and Service: The Court has subject matter jurisdiction over Shionogi's claims pursuant to 28 U.S.C. § 1332 because Plaintiff Shionogi is a citizen of Japan and Defendant InterMune is a citizen of Delaware and/or California, and the matter in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs. Personal jurisdiction and venue have not been contested, and InterMune has been properly served.

2. Facts:

Joint Statement: Idiopathic Pulmonary Fibrosis ("IPF") is a rare, progressive and fatal lung disease of unknown cause. Shionogi and InterMune have certain rights, in their respective territories, to develop and commercialize the chemical compound Pirfenidone for the treatment of IPF, as well as other fibrotic diseases. In 2004, Shionogi and InterMune entered into an agreement known as the Collaboration Agreement, which they amended in 2010 ("Agreement"), relating to their development of Pirfenidone.

Plaintiff's Statement: Pursuant to the Agreement, Shionogi and InterMune agreed to exchange certain documents relating to their clinical trials of Pirfenidone. In addition, if either party's documents are to be used as Pivotal Study Data in a New Drug Application ("NDA"), the parties agreed to an exclusive royalty bearing license. In 2010, InterMune used Shionogi's phase 3 clinical trial of Pirfenidone ("SP3") as Pivotal Study Data in InterMune's European Union NDA. In 2011, InterMune obtained approval to market Pirfenidone throughout the European Union. Pursuant to the Agreement, InterMune owes Shionogi royalties on InterMune's Net Sales of Pirfenidone throughout the European Union.

Defendant's Statement: Pursuant to the Collaboration Agreement, Shionogi and

1 InterMune exchanged certain documents relating to their clinical trials of pirfenidone. The
2 parties reciprocally agreed that those documents could be “freely” used by the other party,
3 without any royalty obligation, for a variety of purposes, including in an NDA seeking
4 governmental approval to market pirfenidone. The Collaboration Agreement does not require
5 royalties to be paid, except in the narrow set of circumstances specified in Section 3.4.4 thereof.
6 In 2010, InterMune filed an NDA in the European Union and in 2011 received European
7 Commission approval to market pirfenidone for the treatment of IPF. Neither the content of
8 InterMune’s NDA filing nor the European Commission’s approval of that filing satisfied the
9 conditions to a royalty obligation stated in Section 3.4.4. Accordingly, InterMune was permitted
10 to “freely” use Shionogi’s clinical documents, and no royalties are owed.

11 **3. Legal Issues:** The central legal issue is the proper construction of the Agreement,
12 particularly the meaning of Article 1.3 and the royalty provisions. An additional legal issue is
13 whether InterMune had a duty to exercise reasonable efforts or due diligence to use Shionogi’s
14 data as Pivotal Study Data in its EU NDA.

15 **4. Motions:** The parties anticipate filing dispositive motions for summary judgment
16 after the close of expert discovery, and discovery motions as needed.

17 **5. Amendment of Pleadings:** Shionogi filed its First Amended Complaint on Friday,
18 August 31, 2012. Shionogi may file further amendments alleging InterMune’s use of Shionogi’s
19 clinical studies of Pirfenidone as Pivotal Study Data in new drug applications in other
20 jurisdictions. InterMune answered the First Amended Complaint on September 17, 2012. The
21 parties jointly propose a pleading amendment deadline of March 15, 2013.

22 **6. Evidence Preservation:** The parties agree that all evidence related to the current
23 action be preserved by the parties, including any electronically-stored information.

24 **7. Disclosures:** The parties exchanged initial disclosures on October 5, 2012.

25 **8. Discovery:** Shionogi served its first request for production of documents and first
26 set of interrogatories on September 18, 2012. Shionogi’s discovery will focus on (i) the
27 Collaboration Agreement, including negotiation, performance, interpretation and enforcement,
28 (ii) InterMune’s EU NDA, (iii) Shionogi’s damages, and (iv) InterMune’s use of Shionogi’s

clinical documents in InterMune's regulatory filings or planned regulatory filings. On October 18, 2012, InterMune served responses and objections to Shionogi's discovery. InterMune served its first request for production of documents and first set of interrogatories on October 23, 2012. The focus of InterMune's discovery requests will include communications and other documents relating to: (i) the Collaboration Agreement, including the negotiation and drafting thereof and the parties' performance thereunder; (ii) InterMune's EU NDA; (iii) Shionogi's use of InterMune's clinical documents in its own regulatory filings; and (iv) the design and conduct of, and deficiencies in, Shionogi's clinical trials.

The parties agree that entry of a protective order will be necessary to protect from public disclosure private and commercially sensitive or trade secret information that may be produced in this action. The parties have agreed on the [Proposed] Stipulated Protective Order attached at Exhibit A to this Joint Case Management Conference Statement, and respectfully request that the Court enter this Order.

The parties agree to and propose the following modifications of the discovery rules:

	Parties' Proposal
Interrogatories	25
Depositions	15 per party (excluding experts)
Requests for Admissions regarding genuineness of documents	Unlimited
Requests for Admissions regarding facts, application of law to facts, or opinions about either	50
Requests for Production of Documents	Unlimited
Custodians	20 per party ¹

The parties agree that all documents, including electronically stored information ("ESI"), be produced in the production format identified in Exhibit B to this Joint Case Management Conference Statement.

¹ This does not relieve the parties of their duty to search and collect from central files or databases.

1 To help control review costs, the parties agree to use mutually acceptable search terms (in
 2 all relevant languages) and date restrictions to filter any collections of ESI, including foreign
 3 language ESI. In addition, the parties agree to take reasonable steps to identify any relevant
 4 subject-specific collections of ESI, including foreign language ESI, and to review any relevant
 5 subject-specific collections of ESI in their entirety. For example, if custodian A has a relevant
 6 subject-specific e-mail folder (e.g., InterMune Collaboration) for all emails sent and received
 7 relating to the Collaboration Agreement and custodian B has only a central repository for all
 8 emails sent and received on all subjects, then search terms and date restrictions would be used on
 9 both custodians, but any emails in custodian A's subject-specific email folder not otherwise
 10 captured by the search terms and date restrictions would also be reviewed for possible production.

11 **Foreign Language Documents and ESI:**

12 The parties agree that the review and translation of foreign-language documents will be
 13 necessary in this case, but disagree on the process for the review and translation of such
 14 documents. The parties request permission to submit letter briefing on these topics.

15 *Shionogi's Position:* InterMune requests that all document review to be conducted by US
 16 lawyers or graduates of US law schools based on its speculation regarding the composition of
 17 Shionogi's document review team and the structure of its review processes. To date, Shionogi
 18 has not assembled its document review team or established its review processes and, indeed,
 19 InterMune has yet to serve any discovery. Moreover, Shionogi did not inform InterMune of its
 20 intentions with respect to the composition of its document review team, other than to state that its
 21 document reviewers would be bilingual. It is now a common practice to outsource document
 22 review in complex, global litigation, because it reduces costs and allows for the efficient
 23 provision of labor-intensive legal services. It is well-established that lawyers may outsource legal
 24 or nonlegal support services provided the lawyer remains ultimately responsible for rendering
 25 competent legal services. Japanese/English bilingual document reviewers are scarce resources,
 26 even more so if limited to US attorneys. Jones Day, more than most firms, has access to
 27 resources to ensure the document review team's adequate supervision, including bilingual
 28 attorneys located in its Tokyo office. Shionogi merely asks that the Court not limit the available

1 options based on InterMune's speculative and unsupported request.

2 With respect to translations and summaries of foreign-language documents, InterMune has
3 proposed to Shionogi a one-sided process that invades Shionogi's work product and requires
4 Shionogi to provide its translations but no corresponding duty on InterMune's part to provide its
5 summaries and translations to Shionogi. Before any ruling on the translation issue, Shionogi
6 respectfully requests the Court's permission to submit a brief presenting its position.

7 *InterMune's Position:* InterMune believes that Shionogi's proposed process for review
8 and translation of foreign-language documents is insufficiently reliable and would be unfair to
9 InterMune. Shionogi has informed InterMune that it (1) may have foreign lawyers or non-
10 lawyers review the original foreign-language material, and (2) does not intend to have the
11 majority of that material translated, even for its own U.S. counsel. Under that approach, an
12 inestimable number of documents will neither be reviewed, nor *capable* of being reviewed, by
13 attorneys familiar with U.S. law and discovery practices and with professional responsibilities to
14 this Court. While outsourcing may in some instances comply with the ethics rules, such that U.S.
15 counsel will be fulfilling their responsibilities to their client Shionogi, the specific outsourcing
16 process that Shionogi asks the Court to keep open as an "available option" would not comply
17 with Shionogi's obligations to provide the discovery required by Fed. R. Civ. P. 26 and 34. There
18 is simply no way to know how many discoverable documents would slip through without
19 adequate review. Accordingly, InterMune proposes that (1) all document review be conducted by
20 lawyers admitted to the bar of a State of the United States;² and (2) without being obliged to
21 create translations, the parties be required to produce English translations of foreign-language
22 documents to the extent such translations exist at the time the foreign language document is
23 produced. InterMune requests the opportunity to submit a letter brief regarding Shionogi's claim
24 of work product with respect to translations.

25 **Location of Depositions for Foreign Deponents:** The parties agree to meet and confer
26 regarding the location of depositions of foreign deponents as necessary (whether affiliated with

27 ² To accommodate junior lawyers, also acceptable are graduates of a law school in the
28 United States who have (a) taken such a bar exam, and (b) either have not yet received the results
or have passed but not yet been admitted.

1 Shionogi, InterMune or third parties), with the goal of minimizing travel and expense, if possible.
2 If the parties are unable to resolve any disputes on this issue, they will request the Court's
3 assistance.

4 Shionogi's position is that there is no ripe dispute regarding the location of depositions.
5 No deposition notices have been served by either party, the identity of proposed deponents is not
6 yet known and neither party has agreed or refused to make any witness available in any location.
7 Shionogi notes that, while there are procedures governing them, depositions are permitted in
8 Japan and it is not clear that witnesses, regardless of their position, can lawfully be compelled to
9 travel outside of Japan for deposition. Thus, it is possible that Shionogi will take the position that
10 at least some depositions should occur in Japan. In addition, Shionogi understands that there are
11 also legal restrictions on the taking of depositions in the EU, which may limit Shionogi's ability
12 to depose InterMune witnesses. Shionogi agrees to meet and confer on these issues, if and when
13 they become ripe, and to present unresolved issues to the Court if and when necessary.

14 It is InterMune's position that, in light of legal restrictions on the taking of depositions in
15 Japan, Shionogi should be required to make its witnesses available outside of Japan. It is obvious
16 that Shionogi employees will need to be deposed in the litigation; indeed, many Shionogi
17 employees are named in Shionogi's initial disclosures. Shionogi should not be permitted to use
18 Japanese law to shield its employees from deposition in this U.S. litigation. Shionogi's
19 suggestion that it cannot "compel[]" its witnesses to travel outside Japan raises concerns about its
20 willingness to make those witnesses reasonably available to be deposed. For its part, InterMune
21 will commit to requiring any of its employees in Europe to travel to a jurisdiction in which
22 depositions are permitted. It would greatly facilitate discovery to have the rules of the road be
23 established now.

24 **Privilege Logs:** Privilege logs will be due 4 weeks after each production, except that all
25 privilege logs will be due by the close of fact discovery. The parties agree that the parties need
26 not log communications with outside counsel or communications on or after the date the
27 complaint was filed.

28 **9. Class Actions:** N/A

1 **10. Related Cases:** N/A

2 **11. Relief:** Shionogi seeks its damages, i.e., the outstanding royalties due and owing
 3 on InterMune's Net Sales of Pirfenidone in the European Union, its attorneys' fees in accordance
 4 with the attorneys' fees provision in the Collaboration Agreement and specific enforcement of the
 5 royalty provisions. Shionogi seeks a declaration that (1) InterMune is obligated to pay royalties
 6 on all sales of Pirfenidone in the European Union; (2) Whether clinical trial documents are used
 7 as Pivotal Study Data is dependent on the party's conduct and independent of a regulatory
 8 authority's use or analysis of the clinical trial documents; and (3) an exclusive licensee under the
 9 Collaboration Agreement has a duty to exercise reasonable efforts or due diligence to use the
 10 licensor's IPF clinical trial documents as Pivotal Study Data.

11 InterMune seeks dismissal of all claims in Shionogi's First Amended Complaint with
 12 prejudice, plus its costs and fees incurred in this action, including reasonable attorneys' fees,
 13 expert witness fees and out-of-pocket costs pursuant to Section 6.4 of the Collaboration
 14 Agreement.

15 **12. Settlement and ADR:** The parties had their ADR Phone Conference on October
 16 11, 2012. The parties are willing to engage in a non-binding private mediation in the next few
 17 months. If the initial ADR process does not resolve the litigation, Shionogi believes that the
 18 parties should engage in a second ADR process after the close of fact discovery and no later than
 19 September 16, 2013. InterMune considers it premature to form a view on whether ADR would be
 20 useful after the close of fact discovery.

21 **13. Consent to Magistrate Judge for All Purposes:** Both parties consented to
 22 Magistrate Judge Laporte on August 13, 2012.

23 **14. Other References:** The parties agree that this case is not suitable for reference to
 24 binding arbitration, a special master, or the Judicial Panel on Multidistrict Litigation.

25 **15. Narrowing of Issues:** The parties agree that it would be premature to discuss
 26 expediting the presentation of evidence at trial. The parties propose that this issue be addressed at
 27 a later Case Management Conference following the close of expert discovery.

28 **Bifurcation of Discovery and Trial:** InterMune proposes that proceedings with respect

to damages—including discovery—should be deferred until the resolution of proceedings with respect to liability. It is InterMune’s position that, because damages issues in this matter are complex and entirely distinct from the question of liability, bifurcation will serve the interests of economy and expedience. Shionogi’s position is that a separate trial of liability and damages is not justified because the damages issues in this matter are uncomplicated and therefore do not merit the duplication of effort entailed by two phases of discovery and dispositive motions and two trials. If the Court desires, the parties will present their positions in letter briefs.

16. Expedited Trial Procedure: The parties do not believe this case is suitable for the Expedited Trial Procedure under General Order No. 64.

17. Scheduling: Plaintiff and Defendant separately propose the following schedules for discovery, expert disclosures, dispositive motions and trial of the action below.

	Plaintiff’s Proposal	Defendant’s Proposal³
Initial Disclosures	October 2, 2012	October 2, 2012
Deadline to File Motions to Join Parties	November 15, 2012	November 15, 2012
ADR 1	by December 31, 2012	N/A
Deadline for filing motion or stipulation to Amend Pleadings	March 15, 2013	March 15, 2013
Supplemental Rule 26(e)(1) Disclosures (as required by Magistrate Laporte’s standing order)	May 31, 2013	June 14, 2013
Close of Fact Discovery	June 28, 2013	July 12, 2013
Identification of Opening Experts and Subjects of Testimony	July 5, 2013	July 19, 2013
Deadline for Filing Motion to	July 5, 2013	July 19, 2013

³ In order to show a more meaningful comparison to Shionogi’s proposal, InterMune’s proposal assumes that discovery and trial regarding damages will not be bifurcated. Should the Court agree with InterMune that bifurcation is appropriate, InterMune will work with Shionogi to propose appropriate modifications.

	Plaintiff's Proposal	Defendant's Proposal³
Compel (as required by Local Rule 37-3)		
Opening Expert Reports	July 31, 2013	August 14, 2013
Rebuttal Expert Reports	August 28, 2013	September 11, 2013
Close of Expert Discovery	September 30, 2013	October 15, 2013
ADR 2	by September 30, 2013	N/A
Deadline for Filing Motion to Compel Expert Discovery (as required by Local Rule 37-3)	October 7, 2013	October 21, 2013
Deadline for Hearing Dispositive Motions	November 26, 2013	December 10, 2013
Deadline for Lead Trial Counsel to Meet and Confer (1) Joint Pretrial Conference Statement, (2) Preparation and exchange of pretrial materials, and (3) settlement of action	January 13, 2014	January 13, 2014
Deadline to File Joint Pretrial Conference Statement	January 28, 2014	March 4, 2014
Deadline to file trial briefs and motions in limine	January 28, 2014	March 4, 2014
Deadline to file proposed voir dire questions, jury instructions and verdict forms	January 28, 2014	March 4, 2014
Deadline to file excerpts from discovery that will be offered at trial (including designations of deposition testimony)	January 28, 2014 (deposition designations will be exchanged between the parties no later than January 17 and counter-designations no later than January 24, so that all designations of a deponent can be filed in one	March 4, 2014 Affirmative designations will be exchanged between the parties no later than February 3, 2014. Counter-designations will be exchanged no later than February 24, 2014.

	Plaintiff's Proposal	Defendant's Proposal³
	document)	
Deadline to file exhibits setting forth the qualifications and experience of each expert witness	January 28, 2014	March 4, 2014
Deadline to file list of each party's exhibits and to exchange premarked exhibits and deliver two sets to chambers	January 28, 2014	March 4, 2014 A list of such exhibits will be exchanged between the parties no later than February 3, 2014.
Deadline to file objections to exhibits or deposition excerpts or other discovery	February 7, 2014 (objections will be exchanged between the parties no later than January 31 and responses to objections will be exchanged no later than February 5)	March 14, 2014 Objections to affirmative deposition designations and exhibits will be exchanged between the parties no later than February 24, 2014. Objections to counter-designations will be exchanged between the parties no later than March 8, 2014.
Deadline to file objections to non-expert witnesses	February 7, 2014	March 14, 2014
Deadline to file objections to proposed voir dire questions, jury instructions, and verdict forms	February 7, 2014	March 14, 2014
Deadline to file oppositions to motions in limine	February 7, 2014	March 14, 2014
Deadline for Supplemental Rule 26(e) Disclosures	February 7, 2014 (needed to update damages calculations)	March 14, 2014
Pretrial Conference	February 25, 2014	March 24, 2014
Trial Date	March 10, 2014 (7 court days)	April 7, 2014 (7 court days)

18. **Trial:** The parties have demanded a jury trial on all claims so triable. The length of a trial at this time is uncertain, but a reasonable estimate is approximately 7 court days.

1 **19. Disclosure of Non-Party Interested Entities or Persons:** Each party filed the
2 required disclosure of non-party interested entities or persons, and neither party had any entity or
3 person to disclose.

4 **20. Other Matters:** The parties identify no other matters at this time.

5
6 Dated: October 23, 2012

Jones Day

7 By: /s/ Jason McDonell
Jason McDonell

8 Attorneys for Plaintiff
9 SHIONOGI & CO., LTD.

10
11 Dated: October 23, 2012

CRAVATH, SWAINE & MOORE LLP

12 By: /s/ Gary A. Bornstein
Gary A. Bornstein

13 Attorney for Defendant
14 INTERMUNE, INC.

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17 **CIVIL L.R. 5(i)(3) ATTESTATION OF CONCURRENCE OF SIGNATORIES**

18 I, Jason McDonell, am the ECF user whose identification and password are being used to
19 file this Stipulation. Pursuant to Civil L.R. 5(i)(3), I hereby attest that Gary A. Bornstein, counsel
20 for Defendant, has concurred in the filing of this document.

21 Dated: October 23, 2012

Jones Day

22 By: /s/ Jason McDonell
23 Jason McDonell

24 Attorneys for Plaintiff
25 SHIONOGI & CO., LTD.